

ATTORNEY DOCKET NO. 37629-0076US

REMARKS

Prior to entry of the foregoing amendment, claims 1 and 16-46 were pending. Applicant respectfully requests entry of the foregoing amendments on the basis that they adopt suggestions made by the examiner, require no further search, and place the case in condition for allowance. Upon entry of the foregoing amendments, claims 28-30, 32, 34, 35, and 46 will be canceled without prejudice or disclaimer, claims 1, 25-27, 33 and 43 will be amended, and claims 47-49 will be added. All amendments are supported by the specification as originally filed.

In the February 8, 2005 Office Action, claims 1 and 16-46 were rejected for lack of enablement under 35 USC § 112, first paragraph. Claims 20, 23-33, 36-41 and 43 were rejected under 35 USC § 112, second paragraph, as indefinite. Applicants were required to cancel alleged new matter presented in the amendment filed November 15, 2004.

Rejections under 35 USC § 112

Claims 1 and dependent claims 16-46 are rejected under 35 U.S.C. 112, first paragraph for lack of enablement. Specifically, the Examiner admits that independent claim 1 is enabled for filamentous bacteriophages, but lacks enablement for other "polyphages". Without acquiescing in the Examiner's rejection and merely to expedite allowance of the claims, applicants have adopted the Examiner's suggestion and amended claim 1 to recite filamentous polyphage particles, thereby obviating the rejection.

Claims 20, 23-33, 36-41, and 43 are rejected under 35 U.S.C. 112, first paragraph, for lack of enablement. Specifically, the Examiner has rejected claims 23, 33 and 36-44 on the grounds that there allegedly is no uniform gene organization or gene nomenclature that applies to all filamentous phages.

Applicants respectfully traverse. Filamentous phages, including f1, fd, M13, f1, ZJ/2, Ec9, AE2, HR, Jf1, Jf2 or X are a class of bacteriophages that share a common structure. The virion consists of a flexible helical capsid enclosing a single strand of circular DNA. The capsid is composed of a single protein species (gVIII), except for a few molecules of minor proteins. At the leading end of the phage particle (the end that makes contact with the target cell surface in infection) is the adsorption protein, gVI; at the opposite end are gIII and gIX. Adsorption occurs

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at the tips of pili determined by conjugative plasmids. Phages fl, M13 and fd all attach to the F-pili.

As reported by Frederick C. Neidhardt, "Escherichia coli and Salmonella, Cellular and Molecular Biology", Volume 2, page 2327, the following gene/protein structure applies to filamentous phages:

Gene	Protein
I	Assembly protein
II	Initiator of rolling-circle replication; nicks and seals DNA at specific sites
III	Minor coat protein at leading end of virion
IV	Assembly protein
V	ss DNA-binding protein
VI	Minor coat protein at leading end of virion
VII	Minor coat protein at virion terminus
VIII	Major coat protein
IX	Minor coat protein at virion terminus
X	Potential inhibitor of gII

Using this standard nomenclature the skilled person in the art can clearly understand the meaning of gene II, gene III and gene VIII, for example. Furthermore, the skilled artisan will understand that it is common practice to use vectors derived from filamentous phages. For example, a phage vector typically is a vector derived by modification/mutation of a phage genome, containing an origin of replication for a bacteriophage; a phagemid vector typically is a vector derived by modification/mutation of a plasmid genome, containing filamentous bacteriophage sequences, e.g. an origin of replication as well as the plasmid origin of replication. Accordingly, withdrawal of the rejection of claims 23, 33 and 36-40 respectfully is requested.

Similarly, the Examiner rejects claim 24, "IR1" and "IR2" as being meaningless for the scope of the generic polyphage. Applicants respectfully traverse.

Again, the person skilled in the art working in the field of bacteriophages will recognize that phages "IR1" and "IR2" are characteristic names specifying particular mutants of phages (see, e.g., Enea & Zindler, Virology 122 (1982), 222-226), as explained in detail in the

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specification on page 7, for example. Furthermore, since applicants have amended the claims to cover "filamentous bacteriophages", withdrawal of the rejection of claim 24 respectfully is requested.

Claim 33 is rejected under § 112, second paragraph, as indefinite. Specifically, the Examiner alleges that claim 33 fails to specify if the recited amber mutation is anywhere in the vector or in gene VII. Applicants have amended claim 33 to clarify that the amber mutation occurs in gene VII of vectors containing gene VII, thereby obviating the rejection.

Claims 20, 25, 26 and 40 also are rejected as indefinite for reciting, "mutated sequences" or a "mutant thereof". Applicants respectfully traverse.

The skilled person in the art working with recombinant DNA will understand that a mutant or a derivative is a substance that is derived from a polypeptide, which is encoded by the DNA. The mutant may differ from the encoded polypeptide by the addition, deletion, substitution or insertion of amino acids. These changes at different positions in the sequence may be made preferably at the nucleotide level. Mutation methods are described, for example in Kay et al., Phage Display of Peptides and Proteins: A Laboratory Manual, Academic Press, San Diego, 1996. Additionally, selective mutations at predetermined sites may be performed using standard molecular biological techniques (Sambrook et al., Molecular Cloning: A Laboratory Manual, Cold Spring Harbour Press, 1989).

Claim 20 refers to a mutation in the ColE1 plasmid origin of replication. Page 7 of the specification explains in detail that plasmid incompatibility is connected to the presence of incompatible plasmid origins of replication belonging to the same incompatibility group. Therefore, one of the ColE1 plasmid origins of replication often includes a mutation. Since also the plasmid origin of replication ColE1 is known in the art, the skilled artisan will know how to introduce mutations into the respective sequence and arrive at the claimed invention. Accordingly, withdrawal of the rejection of claim 20 respectfully is requested.

Claims 25 and 26 refer to mutants of fl-, fd- and/or M13 sequences. As explained above, the person skilled in the art will be able to introduce mutations into DNA sequences according to the general knowledge in the art and prepare derivatives or mutants. Furthermore, the mutants are explained in more detail in the specification on page 8 and 9, example 2, especially page 19 with reference to fpep3_1B-IR3seq; the sequence of the phage vector is disclosed as SEQ ID NO: 31, figure 4. The phage vectors and phagemid vectors described in the specification and

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disclosed in the claims are derivatives and/or mutants (carrying for example the origin of replication of the filamentous bacteriophage fpep3_1B-IR32seq) of the DNA sequence disclosed as SEQ ID NO: 31. Accordingly, withdrawal of the rejection of claim 25 and 26 respectfully is requested.

Claim 40 refers to the truncated gIIIp being a mutant of phage fCA55. In the filamentous phage system, a wide range of vectors is available (see, Kay et al., supra). For the display of proteins on the surface of bacteriophage particles, gene III is commonly used for the insertion of foreign gene. Furthermore, the foreign gene can be inserted directly into the phage genome or into a phagemid vector. The mutant as disclosed in claim 40 is described in detail in the specification on page 10 with reference to Crissman and Smith (Virology 132 (1984) 445-455) carrying a large deletion in gene III removing the N-terminal domains and a large part of the C-terminal domain. Accordingly, withdrawal of the rejection of claim 40 respectfully is requested.

The rejections of claims 26-28 are overcome by amendments made in these claims. Accordingly, withdrawal of the rejection of claims 26-28 respectfully is requested.

The remaining claims rejected as being indefinite (claims 29, 34, 35, 46) have been canceled without prejudice or disclaimer, in an effort to expedite allowance of the present claims.

The Examiner also has rejected Claims 34, 35 and 46 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. However, as indicated above, applicants have canceled these claims without prejudice or disclaimer, in an effort to expedite allowance of the present claims, thereby mooting the rejection.

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Conclusion

In light of the above amendments and remarks, applicants respectfully submit that the application is in condition for allowance.. Should the Examiner have any questions, the Examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

Dated: June 8, 2005

By: Paul M. Booth
Reg. No. 40,244

Attorney for Applicants

Customer No. 26633
HELLER EHRMAN WHITE &
MCAULIFFE LLP
1717 Rhode Island Avenue, N.W.
Washington, D.C. 20036
(202) 912-2000 (office)
(202) 912-2020 (fax)

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Signature

Paul M. Booth (Reg. No. 40,244)